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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,165	06/12/2000	PATRICK W. GRAY	27866/34810	7556

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EXAMINER	
LI, BAO Q	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,165	GRAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,30,31,38,39 and 42-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-46 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/12/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

IDS

IDS submitted on April 12, 2004 has been acknowledged and considered by the examiner.

Response to Amendment

This is a response to the amendment, paper No. 24, filed 05/13/2004. Claims 26 and 42 and 43 have been amended. Claims 1-25, 27-29, 32-37 and 40-41 have been canceled. New Claims 46-54 are added. Claims 26, 30-31, 38-39, 42-54 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New matter

The amendment filed paper no. 24, 0/13/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claims 52-54, which are directed to a method of palliating an allergic reaction by using a MDC antagonist (claim 26) further comprising administering a TARC antagonist compound, which is an antibody or humanized anti-TARC antibody, specifically binding to TARC polypeptide.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 26, 30-31 and 38-43 are moot in view new ground of rejections.

New matter Rejection

2. Claims 52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, newly added claims 52-54 indicating that the method of palliating an allergic reaction by MDC antagonist (claim 26) together with a TARC antagonist compound, which is an antibody or humanized anti-TARC antibody, specifically binding to TARC polypeptide are not disclosed in specification, as it was original filed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 42-46 and 50-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter , which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. The test of scope of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors are analyzed according the situation of the present application.

6. 1) & 2) State of art and unpredictability. It is known in the art that allergy is caused by the infiltration of eosinophils. MDC and TARC share same receptor CCR4.

However, the chemotaxis of eosinophil induced by MDC is CCR4 independent as evidenced by Bocher et al. (J. Allergy Clin. Immunol. 1999, Vol. 103, pp. 527-532). Therefore, it is unpredictable whether MDC or TARC antagonist that blockage of CCR4 is able to inhibit an allergic reaction mediated by filtration of eosinophils. Recently, it is reported by Conrey et al. (J Leukoc Biol. 2003, Vol. 74(4), pp. 558-63) that CCR4+ T cells are recruited to the asthmatic lung in response to allergen challenge; however, blockade of CCR4 with a specific antibody resulted in only minor changes in numbers of CCR4+ Th cells in the bronchoalveolar lavage fluid of allergen-challenged guinea pigs. These data suggest that although CCR4 was originally proposed as a marker of Th2 cells recruited to the lung predominantly, it is still doubt the validity of CCR4 as a therapeutic target in the treatment of asthma (See abstract).

7. 3) & 4) Number of working examples and amount of guidance. The specification only teaches that monoclonal antibodies against human MDC, 252Y and 252Z inhibit CCR4 mediated biological activity. However, Applicants does not teach that TARC antagonist is able to inhibit an allergic reaction in vivo. The specification lacks teaching and does not provide any guidance related how the TARC antagonist is generated.

8. 5) Scope of the claims. The scope of claims read broad with a method for treating allergic reaction by using any or all TARC antagonist.

9. 6) & 7) Nature of invention and lever of the skill in the art. The nature of the invention is related to a novel TARC antagonist that can be used as a therapeutic agent for treating any allergic reaction in animal and human being. The level of the skill is high. The in vitro experiment cannot be extrapolated into a result from an an-vivo test.

10. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 112

11. Claims 44-45 are rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the rejection above. It appears from reading the specification that for a successful

utilizing the method of treating an allergic reaction by using a monoclonal antibody against TARC as a TARC antagonist entailed in claims 44-45, the monoclonal antibody against TARC is an essential element. The specification does not provide a reproducible method to make such monoclonal antibody or point to any direction to obtain such monoclonal antibody. It would require an undue experimentation to enable the invention. Therefore, for claims that need anti-TARC monoclonal antibody, deposit of the monoclonal antibody or a cell line that can generate the monoclonal antibody is required.

12. For the reasons discussed above, it is apparent that the monoclonal antibody specifically recited in the claims are required to practice the claimed invention. As a required element they must be known and readily available to the public or obtainable by repeatable method set forth in the specification, or otherwise readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the cell line/hybridoma, which produces this anti-TARC monoclonal antibody. See 37 CFR 1.801-1808.

13. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

14. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit

15. NOTE THE CURRENT ATCC DEPOSITORY ADDRESS: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209. Applicant is reminded that the following and should amend the specification accordingly. The current address of the ATCC is as follows: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

16. If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

(a) during the pendency of this application, access to the deposits will be afforded to one determined by the commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in the public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposits will be replaced if they should become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

17. In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-37 CFR 1.809 for additional explanation of these requirements.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
July 29, 2004

JAMES HOUSEL 8/9/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600